Are you a new study coordinator or new PhD student? Are you interested in conducting research with human subjects at Penn? Please be sure to attend our IRB 101 Session! Come meet the IRB staff and learn about how the IRB works and how to create & submit applications for your research here at the institution.

During this session, we will discuss the basic requirements (plus special tips and advice!) for every type of submission, including initial applications, continuing reviews, modifications, and reportable events. We will also give an overview of how to use the Human Subjects Research Application (HS-ERA), a secure web-based Penn portal used to submit applications to the IRB for review. Finally, we will cover frequently asked questions and how to address those questions within the context of your own studies.

Concerns about how to seek informed consent in your research? Worried about the new Common Rule requirements?

Come to the IRB’s new Informed Consent Workshop! Learn from a member of the IRB senior team all about barriers to effective informed consent and how to solve them within your research. This workshop will also review the new Common Rule requirements, how to incorporate them in the informed consent form, and considerations for how to present this information as well.

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The revised Common Rule has incorporated new required elements of consent, an optional provision for obtaining broad consent, and expansion of the existing exemption categories.

Please come join the IRB staff in discussing the new regulatory landscape pertaining to identifiable information and specimens. This talk will focus on updated requirements to informed consent forms, retrospective chart reviews, registry studies, and future use of data.

Are you being asked to rely on outside IRBs rather than the Penn IRB for your multi-site study? Are you being asked to serve as the single IRB for other sites? This is a session for you.

This session is designed for submitters that are new to the reliance agreement process and will cover the basic requirements for IRB Reliance Agreements (or IRB Authorization Agreements). It will discuss the IRB and the research team roles in the execution of the reliance agreement and while the study is ongoing. This session is designed to educate submitters about the documentation needed to complete the agreements and orient submitters to the Penn IRB’s review process when it serves as the single IRB of Record and as the Relying IRB.

Assessing risk in research can be challenging, especially when the procedures include use of investigational products.

In this session, we will explore how the IRB makes risk assessments, what the IRB is looking for in the submission to be able to make risk assessments and discuss the differences between product determinations of risk and actual assessment of risk as it applies in the individual research submission.